Atty Dkt No. 7035-0004 USSN: 09/823,868 PATENT

AMENDMENT

In the Specification:

Please amend the specification as follows:

Please amend the paragraph beginning at page 7, line 27 as follows:

According to any of the above embodiments, the buffer delivered to the test strip is preferably within a predetermined volume range that the test strip has been designed to process. The predetermined volume range is preferably between about 10 and 250 µL, preferably between about 20 and 200 µL, more preferably between about 20 and 100 µL, and most preferably between about 40 and 60 µL. When a buffer is delivered to the test strip within the predetermined volume range, the terminal sample flow zone may be designed to have a short length from a proximal end to a distal end. For example, when a buffer is delivered to the test strip within a range of about 35 and 45 µL, the terminal flow zone may have a length from a proximal end to a distal end of between about 1 and 25 mm, more preferably 2 and 15 mm, and most preferably 3 and 10 mm.

Please amend the paragraph beginning at page 15, line 25 as follows:

As can be seen from Figures 2A-2D, a feature of the present invention is the control of where and how the buffer flows within the test strip. The buffer delivered to the test strip is preferably within a predetermined volume range that the test strip has been designed to process. The predetermined volume range is preferably between about 10 and 250 µL, preferably between about 20 and 200 µL, more preferably between about 20 and 100 µL, and most preferably between about 40 and 60 µL. When buffer is delivered to a test strip within these ranges, the flow of the buffer stops within the terminal buffer flow zone.

Atty Dkt No. 7035-0004 USSN: 09/823,868 PATENT

Please amend the paragraph beginning at page 16, line 3 as follows:

The terminal buffer flow zone may be designed to have a short length from a proximal end to a distal end. For example, when buffer is delivered to the test strip within a range of about 35 to 45 μ L, the terminal buffer flow zone may have a length from a proximal end to a distal end of between about 1 and 25 mm, more preferably 2 and 15 mm, and most preferably 3 and 10 mm.

Please amend the paragraph beginning at page 16, line 13 as follows:

Figure 2E illustrates the addition of a sample 122 to the test strip at the sample addition zone 118 after the buffer has reached the terminal buffer flow zone. The volume of sample added is preferably between about 10 and 250 μ L, preferably between about 20 and 150 μ L, more preferably between about 50 and 150 μ L, and most preferably between about 75 and 125 μ L. It is noted that the most preferred volume of sample to add to a test strip will vary depending on the assay.

Please amend the paragraph beginning at page 21, line 13 as follows:

For the purpose of illustration, assume that the test zone 112 includes a first analyte binding agent and the sample addition zone 118 includes a second analyte binding agent labeled with a detectable marker. Also assume that the test strip is designed such that a buffer volume of 30 µL will cause the buffer to diffuse to but not beyond the test zone 112. Meanwhile, a buffer volume of 50 µL will cause the buffer to diffuse to the distal end of the terminal buffer flow zone 116.

Please amend the paragraph beginning at page 21, line 19 as follows:

If buffer is delivered to the test strip within the 30 - 50 µL volume range, the distal front of the buffer will diffuse past the test zone 112. Distal advancement of the buffer will stop within the terminal buffer flow zone 116. The buffer then flows back in the proximal direction toward the absorbent zone 108 past the test zone 112, thereby prewetting the test strip. When the sample is added, the sample causes the analyte in the sample and the second analyte binding agent to diffuse across the test zone 112. The second analyte binding agent binds to the analyte

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Atty Dkt No. 7035-0004 USSN: 09/823,868

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which in turn binds to the first analyte binding agent immobilized in the test zone 112. Other components in the sample will not bind to the first analyte binding agent antibody since the first analyte binding agent is selective for the analyte. Since the buffer diffuses away from the test zone 112 prior to the sample reaching the test zone 112, the prior addition of the buffer prewets the test strip but the flow of the buffer does not interfere with the flow of the sample within the test strip.

Please amend the paragraph beginning at page 22, line 3 as follows:

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If a buffer volume of less than 30 μ L is delivered (e.g., 25 μ L) to the test strip, the buffer never diffuses to the test zone 112. As a result, the buffer does not prewet the test strip in the test zone 112. When the sample is added, the sample has to flow across a combination of dry test strip and wet test strip which can create variations due to differences in flow rates.

Please amend the paragraph beginning at page 22, line 8 as follows:



If the buffer volume delivered is greater than 50 μ L (e.g., 55 μ L), the buffer will diffuse past the test zone 112 and past the terminal buffer flow zone 116 into the sample addition zone. When too much buffer is added, the test strip could be flooded, thereby interfering with the test strip's operation. Also, in some embodiments, the buffer could cause diffusion of a second analyte binding agent or a competitive agent positioned distal relative to the terminal buffer flow zone 116.